DRAFT STATEMENT OF WORK (6/6/03)

A. BACKGROUND

Sections 4, 5, 6, 8, and 21 of the Toxic Substances Control Act (TSCA) require EPA to screen and evaluate data submitted by industry, the Interagency Testing Committee (ITC), petitioners, and/or other interested parties for the purpose of assessing potential health and environmental hazards and risks of chemicals and biotechnology products, which must often be completed within a short time.

Under the High Production Volume Chemicals Program EPA reviews technical reports prepared by government or the private sector which provide data characterizing potential toxicity and to assess risks associated with various chemical substances. EPA comments on the scientific adequacy of the data, and the report as a whole identifies data gaps and research needs that impact determinations of potential toxicity and risk, and makes these reports available to the public and/or generates hazard/risk summaries and assessments for actions taken by EPA on the chemical or biological substance.

In the performance of these various tasks under TSCA and similar activities under such other statutes as the Asbestos Hazard and Emergency Response Act (AHERA), Emergency Preparedness Community Right-to-Know Act (EPCRA), Safe Drinking water Act, Department of Homeland Security act, Clean Air Act Amendments, and such Executive Orders as #12898 on Environmental Justice, EPA coordinates its actions with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as implemented in the various pesticide programs.

Moreover, under the Design for the Environment (DfE), Use Cluster, Pollution Prevention (PP), and Green Chemistry initiatives of OPPT, EPA conducts comparative risk evaluations of environmental chemicals to identify safer substitutes. Other initiatives during this term of contract may include, but will not be limited to: (1) Toxics Release Inventory (TRI), (2) Persistent Bioaccumulative Toxic Pollutants (PBTs), (3) High Production Volume Chemicals (HPV), and Testing, (4)Voluntary Children's Chemical Exposure Program (VCCEP).

Analyses and assessments of hazard and risk must frequently be conducted under severe time and scope constraints imposed under TSCA Section 5 (premanufacture notification) or because of court-imposed deadlines under Sections 4 (testing), 6 (control) and 21 (petitions). Drafts of completed analyses and risk assessments or reviews may require outside review by scientists in designated disciplines prior to delivery to EPA. Completed assessments and reviews must adhere to relevant Agency guidelines. When necessary, they must be legally defensible and must be able to support regulatory actions by EPA and the Office of Pollution Prevention and Toxics (OPPT) in particular. This diverse evaluation, analysis, review and comment (in the form of separate memoranda or document sections) is collated into packages that support regulatory decisions. The timetable for assembling these assessment packages usually requires coordination, adjustments and changes across the sections, and, in effect, requires the Contractor to be on call for rapid turnaround of small-scale tasks.

EPA must have access to the highest quality personnel, technical expertise, and scientific methodologies to assist in or conduct routine, peak workload, and short-turnaround scientific and technical analysis supporting TSCA and other acts which TSCA may support. This access helps OPPT sustain its regulatory decisions when reviewed by the public, environmental groups, other executive agencies, Congress, or the courts.

B. PURPOSE

To meet these challenges, this contract will provide support for the hazard evaluation, risk screening and assessment functions of OPPT.

The purpose of this contract is:

1) to support assessment, through compilation and evaluation of data, of chemicals, and biotechnology products examined by OPPT. Assessments range from screening level evaluations that typically use readily available data to more detailed evaluations that assess and integrate hazard, dose response, exposure, and potential risks to health and the environment. These activities also can include preparation of reports, identification of testing needs for chemicals and biotechnology products, development and evaluation of test protocols, and support for extensive data examination.

2) to improve the quality and consistency of EPA's science by providing timely expert review, and assist in the preparation of (1) Specific and generic hazard, dose response, and risk assessment documents including those dealing with comparative risk; (2)Test guidelines and standards for developing adequate test data to characterize the health and environmental effects of chemicals and biotechnology products; and (3) analyses of scientific issues dealing with hazard, risk, and comparative risk that arise in the course of assessments and Agency regulatory decisionmaking.

3) to provide automatic data processing support and information management support to organize and track submitted data and OPPT evaluations of these data; to provide expertise in software systems for the creation and maintenance of data bases; and to provide presentation materials for completed assessments, expert reviews, and data bases.

4) the Contractor will comply with all applicable requirements of the EPA Order 2100 as called for under Section 508 of the Rehabilitation Act.

C. STAFFING

The contractor shall be able to perform all of the tasks set forth below. The contractor shall provide a stable team of professional level scientists and management and support staff to perform chemical and biotechnological assessment and related Work Assignments. As requested, the contractor shall provide the expertise of prominent nationally recognized expert scientists particularly knowledgeable in selected chemicals or biological organisms, disciplines, and areas

identified by Work Assignments. The contractor shall manage and support these experts so that the performance of Work Assignments occurs in timely and coordinated fashion.

The contractor shall provide expertise in the following areas:

Biochemistry
Biostatistics
Biotechnology/ Genetic Engineering
Chemical Fate
Chemistry
Clinical Microbiology
Microbial Systematics
Computer Systems
General Toxicology
Acute, Subchronic, Chronic Toxicology
Developmental Toxicology
Genetic Toxicology
Immunotoxicology
Neuro/Behavioral Toxicology
Oncology
Reproductive Toxicology
Genetic Construct Assessment
Ecology
Aquatic Ecotoxicology
Microbial Ecology
Plant Ecology
Terrestrial Ecotoxicology
Economics
Environmental Risk Assessment Methodologies
Epidemiology
Exposure Assessment - for Chemicals and Biotechnology Products.
Health Risk Assessment Methodologies
Metabolism/Pharmacokinetics
Physicochemical Properties
Plant Genetics
Plant Pathology
Structure-Activity Relationships
Technical Data Management
Information Management
Field Data Analysis
Molecular Biology
Industrial Microbiology/Fermentation Technology

D. TASKS

Performance of work under the contract shall be initiated by Work Assignments issued by the Contracting Officer. Work Assignments will be within the scope of work stated in the contract, and will provide instructions defining the problem, available EPA information, sources to be investigated, the manner of evaluation and assessment, and the outputs. The Contractor shall supply the necessary labor, materials, and off-site facilities required for performance of each individual Work Assignment. Because timeliness and efficient use of resources are of the utmost importance, contractors may at times be required to work on site at EPA Headquarters and other government-provided locations. In addition to being scientifically sound, the reports must adhere to Agency criteria for public communications, being clear, concise, transparent and reasonable.

The contractor shall perform the following tasks as required by specific work assignments:

1(a). Screening

Screening is conducted on chemical and biotechnology product data received by OPPT. The contractor shall perform screening level assessments. Additional work may include triage of submitted studies and analyses using structure-activity relationships. Tracking of these screening activities shall also be maintained. Screening encompasses reviews at limited levels of effort from limited, generally readily available, information without extensive research or evaluation.

1(b). Assessments for Chemicals and Biotechnology Products

The contractor shall prepare health and environmental hazard and risk assessments for OPPT. Analyses may involve the following activities: summary of data; literature and data review; evaluation including validation and analysis of data; determination of sufficiency of data for hazard assessment; identification of data gaps; and determination of effects of concern. As specified by work assignment, the contractor shall prepare statistical analyses, including but not limited to "no-observed(-adverse)-effect-levels" (NO(A)ELs), and dose-response curves. Measures of virulence and genetic construct persistence may be requested for biotechnology products. The contractor may be required to provide computer-assisted aggregation and analysis of scientific and technical data using statistical and deterministic models and other software tools available to the OPPT. Where submitted data are limited (for example as in Section 5 Premanufacture Notices), the Contractor may be required to perform structure-activity analyses with respect to toxicologically important moieties and structural analogues and biotechnology products.

The Contractor shall be able to maintain, develop or modify statistical procedures and methodologies to compile, validate and analyze health and environmental effects research data arising from epidemiologic studies, plant, and animal bioassays, and toxicity tests and structure-activity data.. This may involve the preparation, modification, and/or testing of statistical analysis methods and processing and computation programs. The Contractor shall be able to adjust or

fine-tune statistical packages to better adapt them to Contractor use for OPPT needs. In addition to facility in the Agency's Benchmark Dose Software and Catreg, the Contractor must be able to program in **C++,** VS Fortran, Pascal, and S, to compile and link-edit such programs as the JCL or a similar product, and also to use statistical packages including S+ and R**,** and the Statistical Analysis System (SAS) (resident on mainframe and on personal computer), with each as they may aid in the completion of EPA-required analysis, review, or assessment of toxicologic or epidemiologic data or studies. The ability should extend to use of statistical graphing packages such as SASGRAPH and SYSGRAPH and object- oriented languages which may be used to present various postulated dose-response relationships over a range of dose or exposure levels. In addition, the Contractor may be required to create new statistical algorithms to aid in analysis and assessment. Analyses, assessments and reviews carried out under all the statutory requirements may need to support EPA regulatory actions; consequently, they must be accompanied by full documentation (hard copy and on electronic media; specifics to be given in work assignments) of any methodology used.

The contractor's reviewer shall be available to discuss the results of any review and offer clarification, if needed. These discussions will be via teleconference and/or face to face meetings with EPA scientists.

2. Scientific Issue Resolution

The contractor shall provide the support required to address science issues, comparative risk issues, and/or other science questions of importance to EPA for EPA's development of science policy determinations and statutory decision making. For each issue, or set of questions, identified in Work Assignments, the contractor shall have scientists with expert knowledge of the subject prepare reports that substantively discuss the issue or questions, presenting the various options for resolution and basing the options on the published scientific literature; and these scientists shall attend a round-table discussion with EPA scientists at EPA Headquarters for further information exchange and consensus building.

3. Review Panels/Workgroups/Workshops/Symposia

The contractor shall organize, prepare, conduct, present reports, participate in and/or document the proceedings of Scientific Review Panels, Workgroups, Workshops, or Symposia convened to: l) review health and environmental data to determine the current state of knowledge of adverse health and environmental effects; 2) review state-of-the-art test methods in particular health and environmental areas; 3) perform related information- sharing tasks on health and environmental effects topics of interest to EPA. This effort shall include both administrative support tasks (which are integral to the planning, coordination and conduct of scientific meetings) and technical or scientific support for the preparation of reports and issue papers, as well as acquisition of cited key references and translations. The contractor shall provide administrative support only for tasks that also require technical scientific support under this contract. Support that is not technical in nature includes acquisition of meeting facilities, advance and on site registration, non-technical note taking, court reporter services, and/or acquisition of non-technical meeting facilitation. The contractor shall assist EPA in conducting

various forms of Agency Peer Review of scientific papers and documents.

4. Test Guidelines/Standards

The contractor shall provide support in preparing health and environmental test guidelines and standards in OPPT standard guideline format (see OTS Manual for Preparing Documents, Attachment I) and support documents that include the rationale for testing procedures and conditions for tests. This work may include reviewing existing guidelines and evaluating scientific data concerning the choice of test parameters (including sample sizes to achieve desired specifications), developing and validating new test methods, and formatting and transcribing guidelines based on decisions made by EPA. A quality assurance project plan will be required when the task is to develop or validate new test methods.

5. (a) Automated Data Processing (ADP) and (b) Information Management Support (IMS)

The contractor shall provide technical information management support for intranet and internet information system development. Information systems may require the capturing and processing of external and internal data sources using imaging technology, tracking information (both external and internal) within a system, capturing internal word processing data and/or other electronic generated data as well as external electronic data, archiving data, and possibly disseminating this information via the internet, EPA's Home Web Page, or a Division Home page. The contractor shall provide technical processing support and basic ADP support to complement in-house resources. Technical processing support shall include but not be limited to the initial review of submissions, preparation of data entry forms, and data entry following accompanying Quality Control (Q/C) procedures; internal transmittals; preparation and mailing of acknowledgment letters to submitters; preparation of submission abstracts and data summaries; document imaging support to EPA systems; and maintenance of file integrity. ADP support includes the design, development and maintenance of existing chemical assessment technical support systems, such as small-scale computer systems and office automation systems within the constraints of Office of Information Resources Management (OIRM) policy and contracts. Development of such systems shall be preceded by a feasibility study and requirements analysis.

The Contractor shall provide support that includes, but is not limited to, the following: maintaining existing and developing new information exchange systems; developing management-event tracking systems; developing reporting forms fully contained in computer media; evaluating hardware/software/peripheral combinations for document tracking, review and dissemination. Contractor must be knowledgeable in the construction of databases used for chemical and biotechnology products. This includes familiarity with data formats commonly used for data bases relevant to these products. Contractors shall develop and maintain databases using such software products as: ISIS/Base, Lotus Approach, Lotus Notes, and other standard software as well as provide for data maintained in Genbank and RKC formats used for biological products.

Other Support

The contractor shall aid in defining literature and chemical structure search strategies and performing such searches. These capabilities will be required only to supplement, on an as needed basis, the standard OPPT search capabilities.

As requested in specific work assignments, the contractor shall provide supplemental references and translation acquisition, from a foreign language to English, when essential references are not available within the time limits of a specific assignment through OPPT's standard reference and translation acquisition sources.

As requested in specific work assignments, the contractor shall provide presentation materials of completed assessments, expert reviews, SARs, data bases, resolutions of scientific issues, and test guidelines/protocols. Presentation materials shall include, but not be limited to Power Point presentations, 35-mm slides, overheads, camera-ready graphs and figures, Posters, and covers for EPA publications.